II. REMARKS

Claims 1-2 and 5-17 are currently pending. No amendments to the claims have been made.

A. REJECTION UNDER 35 U.S.C. § 102(b)

In the Office Action, the Examiner rejected claims 1, 2 and 5-17 under 35 U.S.C. §102 (b) as being anticipated by Fallen et al. (U.S. 5,352,456, hereinafter "the '456 patent"). The Examiner stated that "[t]he claims are drawn to a percutaneous formulation comprising an opioid analgesic and a distressing compound."

Before addressing the substance of the rejection, a brief review of the invention is in order. Transdermal devices containing opioid analgesics may be the subject of abuse. In a typical example, an abuser may tamper with the device and extract the opioid analgesic for improper oral or parenteral use. In an effort to deter this problem, the present invention provides a transdermal device which further comprises a distressing substance, which is releasable from the device with the opioid analgesic upon tampering. This would deter abuse, as the distressing substance will provide an aversive effect when orally or parenterally co-administered with the opioid analgesic after tampering. However, the device is formulated in such a manner that the distressing substance is non-permeable through the skin when the patch is applied as directed. In other words, when the patch is applied intact, the distressing substance will remain in the patch and will not be administered to the patient.

With respect to the Examiner's rejection under 35 U.S.C. §102(b), this rejection is traversed. Applicant respectfully submits that the '456 patent, at the very least, fails to teach or suggest a composition for the percutaneous administration of an opioid analgesic comprising a quantity of a distressing substance (e.g., atropine) which is formulated in such a manner that the distressing substance is non-permeable through the skin, as recited in the present claims.

The Examiner refers to column 2, lines 28-46 of the '456 patent, which details a laundry list of possible drugs which are contemplated by the inventors. However, the '456 patent does not teach or suggest any specific combinations of these drugs. Moreover, Applicant respectfully points out that the atropine of the '456 patent is intended to be the active component, and therefore is necessarily permeable through the skin. In sharp contrast, the distressing substance as recited in the present claims, is formulated in a such a manner that it is necessarily non-permeable through human skin and will not cause any physiological effect.

The manner in which the distressing substance is formulated in the composition, i.e., its non-permeablility through human skin when applied transdermally, but its ability to produce an aversive effect when ingested orally or parenterally, is a physical limitation of the invention which imparts patentability to the present claims. Therefore, as this is a physical limitation of the invention, it is not a future intended use as suggested by the Examiner.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be removed.

III. CONCLUSION

In view of the foregoing, Applicants believe that the above-referenced rejections have been obviated and respectfully request that the rejection be withdrawn. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,

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